HiBiScrub® is an antimicrobial skin cleanser containing 4% w/v Chlorhexidine gluconate

Long-lasting sustained protection
Chlorhexidine gluconate, the active ingredient in HiBiScrub binds to the skin forming an effective barrier that will keep killing bacteria and protecting long after application, showing up to 6 hours residual effect¹ and increased efficacy upon repeated application.²

Effective kill rate on many HAI’s in 1 minute
HiBiScrub has an impressive kill rate of within 1 minute for many organisms that are implicated with healthcare associated infections.³ The active, Chlorhexidine gluconate is also extremely effective against a wide range of Gram positive and Gram negative bacteria, yeast, fungi and viruses.⁴

Kind to skin
Containing a blend of emollients, dermatologically tested HiBiScrub helps soften and hydrate the skin. Proven to be significantly less irritating than a leading 4% Chlorhexidine gluconate solution, HiBiScrub also reduces moisture loss even with frequent use.⁵,⁶

Short and effective contact times
Proven short contact times on listed test standards. HiBiScrub kills several Gram positive and Gram negative organisms that are resistant to some of the most widely used antibiotics in as little as 15 seconds.⁷

Effective kill rate on many HAI’s in 1 minute
4% Chlorhexidine gluconate is more effective than PVPI or triclocarban medicated soap⁸ and can be used as part of a care bundle to help reduce surgical site infections. In a recent study, whole body washing with HiBiScrub in conjunction with a nasal antibiotic reduced the risk of hospital associated S aureus infections by nearly 60%.⁹

<table>
<thead>
<tr>
<th>Test standard</th>
<th>Micro organisms</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>EN 1499</td>
<td>E coli</td>
<td>1 minute⁰</td>
</tr>
<tr>
<td>Based on EN 1276</td>
<td>P aeruginosa</td>
<td>10 seconds⁷</td>
</tr>
<tr>
<td></td>
<td>P aeruginosa (multi-antibiotic resistant strain)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>A baumannii (multi-antibiotic resistant strain)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>E coli</td>
<td></td>
</tr>
<tr>
<td></td>
<td>VRSA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>E faecalis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ESBL producing E coli</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ESBL producing E cloacae</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ESBL producing E aerogenes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>ESBL producing K pneumoniae</td>
<td></td>
</tr>
<tr>
<td></td>
<td>S aureus</td>
<td>30 seconds⁷</td>
</tr>
<tr>
<td></td>
<td>E faecium</td>
<td>1 minute¹⁰</td>
</tr>
<tr>
<td></td>
<td>VISA</td>
<td>3 minutes¹⁵</td>
</tr>
<tr>
<td>Based on prEN 12054</td>
<td>EMRSA 15 and 16</td>
<td>1 minute¹</td>
</tr>
<tr>
<td>EN 1040</td>
<td>Staphylococcal aureus and Pseudomonas aeruginosa</td>
<td>1 minute²</td>
</tr>
<tr>
<td>Based on prEN 12054</td>
<td>E hirae</td>
<td>1 minute¹⁵</td>
</tr>
<tr>
<td>EN 1275</td>
<td>C albicans yeastcidal and fungicidal</td>
<td>5 minutes¹¹</td>
</tr>
<tr>
<td>DIS/TSS-7 [EPA method]</td>
<td>H5N1 Avian Flu [NIHBRG-14 construct]</td>
<td>20 seconds¹⁶</td>
</tr>
<tr>
<td>ASTM E1052-99</td>
<td>Influenza A H1N1[Swine Flu variant VR-333]</td>
<td>30 seconds¹⁴</td>
</tr>
</tbody>
</table>
4.1 Therapeutic indications
HibiScrub is an antimicrobial preparation for pre-operative surgical hand disinfection, antiseptic handwashing on the ward and pre-operative and post-operative skin antisepsis for patients undergoing elective surgery.

4.2 Posology and method of administration
For external use only.

Pre-operative surgical hand disinfection. Wet the hands and forearms, apply 5 ml of HibiScrub and wash for 1 minute cleaning the fingernails with a brush or scraper. Rinse, apply a further 5 ml of HibiScrub and continue washing for a further 2 minutes. Rinse thoroughly and dry.

Antiseptic handwash on the ward. Wet the hands and forearms, apply 5 ml of HibiScrub and wash for 1 minute. Rinse thoroughly and dry.

Pre-operative skin antisepsis for the patient. The patient washes his whole body in the bath or shower on at least 2 occasions, usually the day before and the day of operation as follows:

The day before operation the patient washes with 25 ml of HibiScrub beginning with the face and working downwards paying particular attention to areas around the nose, axillae, umbilicus, groin and perineum. The body is then rinsed and the wash repeated with a further 25 ml, this time including the hair. Finally the patient rinses his entire body thoroughly and dries on a clean towel. This procedure should be repeated the following day. Patients confined to bed can be washed with HibiScrub using a standard bed-bath technique.

Conventional disinfection of the operation site will then be performed when the patient is in theatre.

Post-operative skin antisepsis for the patient. The patient washes his whole body, excluding the operation wound, in the bath or shower usually on the third day after operation using the procedure described above.

Children and elderly patients. There are no special dosage recommendations for either elderly patients or children. The normal adult dose is appropriate unless recommended by the physician.

4.3 Contraindications
Known hypersensitivity to the product or any of its components, especially in those with a history of possible chlorhexidine-related allergic reactions (see sections 4.4 and 4.8).

4.4 Special warnings and precautions for use
HibiScrub contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare. HibiScrub should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound (see sections 4.3 and 4.8).

For external use only. Keep out of the eyes and avoid contact with the brain, meninges and middle ear. In patients with head or spinal injuries or perforated ear drum, the benefit of use in pre-operative preparation should be evaluated against the risk of contact. If chlorhexidine solutions come into contact with the eyes, wash out promptly and thoroughly with water.

Do not inject or use in body cavities.

4.5 Interaction with other medicinal products and other forms of interaction
See section 6.2.

4.6 Fertility, pregnancy and lactation
There is no evidence of any adverse effects on the foetus arising from the use of HibiScrub as a handwash during pregnancy and lactation. Therefore no special precautions are recommended.

4.7 Effects on ability to drive and use machines
None have been reported or are known.

4.8 Undesirable effects
Very Common (≥ 1/10), Common (≥ 1/100, < 1/10), Uncommon (≥ 1/1,000, < 1/100), Rare (≥ 1/10,000, < 1/1,000), Very rare (1/10,000), not known (cannot be estimated from the available data).

Skin and subcutaneous tissue disorders:
Frequency not known: Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters.

Immune system disorders:
Frequency not known: Hypersensitivity including anaphylactic shock (see sections 4.3 and 4.4).

4.9 Overdose
This has not been reported.

Accidental ingestion: chlorhexidine taken orally is poorly absorbed. Treat with gastric lavage using milk, raw egg, gelatin or milk oil. Employ supportive measures as appropriate.

5. Pharmacological Properties
5.1 Pharmacodynamic Properties
Mode of action – chlorhexidine has a wide range of antimicrobial activity. Chlorhexidine is effective against a wide range of Gram negative and Gram positive vegetative bacteria, yeasts, dermatophyte fungi and lipophilic viruses. It is inactive against bacterial spores except at elevated temperatures. Because of its cationic nature, chlorhexidine binds strongly to skin, mucosa and other tissues and is thus very poorly absorbed. No detectable blood levels have been found in man following oral use and percutaneous absorption, if it occurs at all, is insignificant.

5.2 Pharmacokinetic Properties
Retention and uptake kinetics and factors influencing the pharmacokinetics.

Chlorhexidine appears to be very poorly absorbed. No blood levels were detected during a 3-week simulated clinical use of HibiScrub.

5.3 Preclinical Safety Data
Chlorhexidine is a drug on which extensive clinical experience has been obtained. All relevant information for the prescriber is provided elsewhere in the Summary of Product Characteristics.

6. Pharmaceutical Particulars
6.1 List of Excipients
- D-glucosamine-delta-lactone
- Isoproxy alcohol
- Lauryl dimethyamine oxide
- Perfume (herbacol 015393 TD)
- Polyoxethyleno-polyoxpropylene block copolymer
- Ponceau 4R (E124)
- Sodium hydroxide
- Glycerol
- Macrogol-7 Glycerol Cooate
- Purified water

6.2 Incompatibilities
Chlorhexidine is incompatible with soap and other anionic agents.

Hypochlorite bleaches may cause brown stains to develop in fabrics, which have previously been in contact with preparations containing chlorhexidine.

6.3 Shelf Life
36 months.

6.4 Special Precautions for Storage
Do not store above 25°C.

6.5 Nature and contents of container
HDPE bottles containing 250 ml, 500 ml and 5 litres.

6.6 Special precautions for disposal and other handling
See section 4.4.

7. Manufacturing Authorisation Holder
Regent Medical Overseas Ltd, Two Omega Drive, Irlam, Manchester, M44 5BJ, United Kingdom.

8. Marketing Authorisation Number
PL 21855/0002.

9. Date of text
February 2013.

References: